



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,998	10/24/2005	Tadahiko Kato	TOYA117.005APC	1401

20995 7590 11/21/2007
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
----------	--------------

1623

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

11/21/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcarter@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/550,998

Applicant(s)

KATO ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,9-12 and 14-16 is/are allowed.
- 6) ☒ Claim(s) 8 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05/17/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 08/29/07.

The amendment filed 08/29/07 affects the application, 10/550,998 as follows:

1. Claims 7-8 have been amended. Claims 1-6 have been canceled. New Claims 9-16 have been added.
2. The responsive to applicants' arguments is contained herein below.

Claims 7-16 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livant et al. (Carbohydrate Research (1992), 237, 271-81) (Abstract Only).

A method of manufacturing a therapeutic agent for nerve damage which comprises dissolving a hyaluronic acid oligosaccharide or a pharmaceutically acceptable salt thereof in a solvent commonly used for drugs, wherein the hyaluronic acid oligosaccharide is selected from hyaluronic acid disaccharide to hyaluronic acid 50-saccharide. Claim 13 is drawn to the method

Art Unit: 1623

according to claim 8, wherein the hyaluronic acid oligosaccharide is hyaluronic acid tetrasaccharide.

Livant et al. disclose an aqueous solution of hyaluronic acid tetrasaccharide (see abstract).

The difference between applicants' claimed method and the method of Livant et al. is that Livant et al. do not exemplify the method of preparation or manufacture of said hyaluronic acid tetrasaccharide. However, Livant et al. disclose that an aqueous solution Livant et al. can be prepared or manufactured. This implies that hyaluronic acid can be dissolved in water to form an aqueous solution. In fact, Livant et al. may have well prepared their aqueous solution.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Livant et al. to prepare or manufacture Livant et al.'s aqueous hyaluronic acid agent or composition by dissolving hyaluronic acid tetrasaccharide in a water (a solvent commonly used for dissolving drugs) in order to use its chemical and physical properties of said hyaluronic acid tetrasaccharide by applying spectrophotometric investigative studies such as NMR, as suggested by Livant et al.

One having ordinary skill in the art would have been motivated to the method suggested by Livant et al. to prepare or manufacture Livant et al.'s aqueous hyaluronic acid agent or composition by dissolving hyaluronic acid tetrasaccharide in a water (a solvent commonly used for dissolving drugs) in order to use its chemical and physical properties of said hyaluronic acid tetrasaccharide by applying spectrophotometric investigative studies such as NMR, since a skilled artisan would reasonable expect to use the composition taught by Livant et al. for the same said purpose.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 7, 9-12, 14-16 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a method of treating nerve damage, comprising administering an effective amount of a hyaluronic acid oligosaccharide or a pharmaceutically acceptable salt thereof to an animal suffering from nerve damage, wherein the hyaluronic acid oligosaccharide is selected from hyaluronic acid disaccharide to hyaluronic acid 50-saccharide. The very relevant prior art document, Atsuta et al., to this invention which treats spinal cord injuries do not teach or suggest the use of the specific hyaluronic acid disaccharide to hyaluronic acid 50-saccharide to treat said nerve damage, nor is it obvious to use said disaccharide to hyaluronic acid 50-saccharide. Furthermore, applicant's declaration under 37 C.F.R. § 1.132 demonstrates that hyaluronic acid disaccharide to hyaluronic acid 50-saccharide have a superior effect compared to hyaluronic acid having larger molecular weight.

Response to Arguments

Applicant's arguments with respect to claims 8 and 13 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1623


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

 11/9/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

November 8, 2007.